FEB - 1 2005

K043168

Section 5
510 (k) SUMMARY

Applicant:	Bisco, Inc. 1100 W. Irving Park Road Schaumburg IL, 60193
Contact Person:	Benjamin Lichtenwalner Tel: 847-534-6146 Fax: 847-534-6111
Date Prepared:	November 15, 2004

Trade Name:	**BISCOVER LV**
Common Name:	Surface Sealant
Classification/Name:	Coating Material for Resin Fillings **Class II per 21 CFR 872.3310**

Description of Applicant Device:

BISCOVER LV is a low viscosity, light-cured resin formulation used to seal restorations and etched enamel while leaving a smooth polished surface. Due to its unique proprietary chemistry, **BISCOVER LV** cures without any sticky oxygen-inhibited layer. **BISCOVER LV** may reduce or even eliminate the need for manual polishing.

Intended uses of Applicant Device:

BISCOVER LV is used to seal and polish direct composites (cured), indirect composites, provisionals, acrylic appliances, Resin-Modified Glass Ionomers, Enamel before or after orthodontic bracket placement, and etched Enamel.

Predicate Devices: BISCOVER Liquid Polish (K030354) dated February 19, 2003.

Significant Performance Characteristics:

BISCOVER LV to BISCOVER Liquid Polish

Property	BISCOVER	BISCOVER LV
Intended use	Resin sealant	Resin sealant
Chemical composition	Light-Cured, Multifunctional Acrylate Resin	Light-Cured, Multifunctional Acrylate Resin
Mechanical /physical properties	Low viscosity clear resin liquid light cured to smooth polish surface	Low viscosity clear resin liquid light cured to smooth polish surface

Side by side comparisons of **BISCOVER LV** to the predicate device **BISCOVER Liquid Polish** clearly demonstrates that the applicant device is substantially equivalent to the legally marketed device. **BISCOVER LV** was tested for biocompatibility and was found to be non-toxic. It is concluded that the information supplied in this submission has proven the safety and efficacy of **BISCOVER LV.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 1 2005

Mr. Benjamin Lichtenwalner
Regulatory Affairs Coordinator
Bisco, Incorporated
1100 W. Irving Park Road
Schaumburg, Illinois 60193

Re: K043168
Trade/Device Name: BISCOVER LV
Regulation Number: 21 CFR 872.3310
Regulation Name: Coating Material for Resin Fillings
Regulatory Class: II
Product Code: EBD
Dated: January 24, 2005
Received: January 25, 2005

Dear Mr. Lichtenwalner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known): K043168

Device Name: BISCOVER LV

Indications for Use:

BISCOVER LV is a low-viscosity, light-cured resin formulation used to seal restorations and enamel while leaving a smooth polished surface.

BISCOVER LV is used to Seal and Polish:

1. Direct composites (cured)
2. Indirect composites
3. Provisionals
4. Acrylic appliances
5. Resin-modified Glass Ionomers
6. Enamel before or after orthodontic bracket placement
7. Etched Enamel

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K043168